REMARKS

Claims 27-32, 34-38 and 40-43 are pending. Claims 27 and 40-41 have been cancelled without prejudice. Claims 36, 37, 42 and 43 are newly amended. Claims 44-47 are newly added.

Claims 42 and 43 are newly amended to more clearly point out the structural design of the recited device, specifically reciting that the collection element is retractable with respect to the outer tube of the device.

Claim 43 has further been amended to remove the recited method step of detecting the presence of HPV in the specimen. Newly added claims 44-47 depend from independent claim 43, and parallel claims 35-38.

Claim 37 is newly amended to remove its dependency on claim 43. Claim 36 is newly amended to remove its dependency from newly cancelled claim 27.

No new matter has been entered.

Interview Summary

Applicant thanks Examiner Geoffrey Hoekstra for the courtesy of a telephone interview with Applicant's Representatives and Inventor Barbara Ducatman on July 23, 2009. The Examiner provided helpful comments and suggestions for proposed claim amendments designed to point out the structural differences of the recited device with respect to the device disclosed by the cited prior art. Suggestions for overcoming rejections related to the drawings were also discussed.

Drawings/Specification

Applicant has provided PDF representations of originally filed Figures 1A and B, cancelled by Applicant in the previous office action. The PDF representations are a higher density scan of the of originally filed Figures 1A and B, thus providing clearer details of the device recited in the instant claims. If these PDF representations do not satisfy the requirements

for Drawings and Figures set forth by the USPTO, Applicant will provide schematic diagrams of these figures, as discussed in the interview.

Claim Objections and Rejections

Claim 40 is objected to because it fails to further limit the subject matter of a previous claim. Accordingly, Applicant has cancelled claim 40, rendering its objection moot.

Claim 42 is objected to because of the following informality: the positive recitation in line 2 of "a vaginal specimen" should apparently read "the vaginal specimen". Accordingly, Applicant has amended Claim 42 accordingly, rendering its objection moot.

Claim 43 is objected to because of the following informality: the positive recitation in lines 2-3 of "a vaginal specimen" should apparently read "the vaginal specimen". Accordingly, Applicant has amended Claim 43 accordingly, rendering its objection moot.

Claim Rejections – 35 USC § 101-Double patenting

The Office action states that should claims 42 and 34 be found allowable, claims 43, 40 and 41 will be objected to as being a substantial duplicate thereof".

Applicant has canceled claims 40-41 and has amended independent claim 43 so that it no longer recites the method step of detecting the presence of HPV in the specimen, thereby removing the overlapping subject matter of independent claim 42 and its dependent claim 34.

Claim Rejections – 35 USC § 102

Claims 27 and 34-38 and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Edens et al. (6,521,190 B1).

Applicant respectfully traverses. Applicant has newly amended the claims to more clearly point out the structural features of the device recited in the claimed method by adding the limitation that the device comprise a collection element and a shield in a form of an outer tube that surrounds said collection element, wherein said collection element comprises a retractable

inner tube which is retractable with respect to said outer tube, and a brush attached to said inner tube . Benefits of this structure include the increased sterility of the sample after collection, and its use by the subject without the need for a healthcare professional.

Anticipation requires that the purported prior art reference disclose each and every limitation of the claims. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Applicant contends that Edens et al. does not teach each and every limitation of the instant claims as newly amended.

Edens et al. teach:

> "A collection apparatus comprising a collection container comprising a first interior portion, second interior portion and third interior portion, wherein the first interior portion of the container extends from an open end to the second interior portion and defines a first central axis; the second interior portion extends inwardly and has a decreasing cross-sectional area from the first interior portion to the third interior portion, and defines a second central axis at an oblique angle with respect to the first central axis, the second interior portion being sized to engage bristles of a brush device having a body of bristles on a shaft and to urge the shaft of the brush device at an angle with respect to the first central axis; the third interior portion extends from the second interior portion and defines a closed end; and the first, second and third interior portions are sized and arranged to form an unencumbered straight line path from the open end to the closed end of the collection container", emphasis added, claim 1. Also see Figure 2 of US6,521,190.

The method of Edens et al. uses a cervical brush which can fit into the collection device and must be completely removed from the collection device when the sample cells are being collected. Accordingly, in the methods taught by Edens et al., the sample is collected with a brush, and subsequent to sample collection, the brush containing the sample is then positioned (and stored) in Edens et al.'s collection chamber with cytology fluid at the bottom of the chamber in such a way that a pipette tip can later access the fluid surrounding the brush without being impeded by the presence of the brush. Thus, the collection element comprising the sampling brush taught by Edens et al. must be separable from the container component of the device.

In contrast, the instant claims require that the brush used for sample collection ***be attached*** to the ***retractable*** inner tube of the recited device. This unitary structure has the net effect that the entire device is used during sample collection. (See Newly added Figures 1A and 1B, and paragraphs 20 and 22 of the published instant application). As depicted in the instant specification:

> "As shown in FIGS. 1A and 1B, the device comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that extend laterally outward from the longitudinal axis. The brush and the inner tube as a whole are called the collection element", paragraph 0020 of the published application, and
>
> "In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, protruding the collection element out to have the bristles contact with the cervical/vaginal tissues, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body. The bristles containing the vaginal sample is then immersed into a liquid collection medium", paragraph 0022 of the published instant application.

Thus, the device used in the method of Edens et al. and the device used in the present method are entirely different. Because the instantly claimed methods for detecting the presence of a human papilloma virus require the use of a device that is structurally distinct from the device used in the methods taught by Edens et al., the teachings of Edens et al are not anticipatory.

The device recited in the instant claims comprises a collection element containing a retractable inner tube, and a brush attached to the inner tube with a longitudinal axis and bristles that are substantially perpendicular to the longitudinal axis of the brush. Further, there is no mention of an inner tube in the device of Edens et al.

Paragraph 16 of the final office action asserts that Applicant's arguments relies on the feature that "the brush must be a separate device" is not recited in the rejected claims. As described above, the instant claims recite that the brush is attached to the inner tube of the device. As such, the brush of the instantly recited brush is not separated from the rest of the

device. In contrast, the brush is a component which is separable from the device described by Edens et al.

> "A cellular sample is typically obtained from the cervix by gently inserting the cytology brush device 200 until only the bristles closest to the shaft or rod 220 are exposed to the cervical tissue. The brush device 200 is then slowly rotated and removed", column 4, lines 29-33, US6,521,190.

Figure 2 of Edens et al. shows that the brush is pointed down towards the closed end of the collection apparatus. Edens et al. states "The collection apparatus 100 includes a collection container 110 including an open end 114, a closed end 116, and an interior wall 112", column 3, lines 20-23. Thus the functional and physical disclosure of the sampling device by Edens et al. clearly indicate that the brush and the collection container are separate, unattached elements.

This retractable feature in the structural design of the device encompassed by the instant claims clearly distinguishes it from the device taught by Edens et al. In view of the claim amendments and remarks, Applicant respectively requests reconsideration and withdrawal of the instant rejection.

Claims Rejections – 35 USC § 103

Claims 28-32 stand rejected as obvious over Edens, in view of Zavada (US2003/0049828).

Applicants respectfully traverse on the grounds that neither Edens et al. alone, nor when combined with Zavada, teach all the limitations of the instant claims as newly amended. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed in the rebuttal to the 102 rejection, Edens et al. does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device where a brush is attached to a retractable inner tube of the collection device, as required by the instant claims.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up for Edens et al.'s not teaching a unitary device as required by the instant claims.

Therefore, Applicants contend that the teachings of Edens et al., either alone or in combination with Zavada et al., do not teach all the limitations of the instant claims. Specifically the limitations that the instantly recited device comprise a collection element with a retractable inner tube, and a brush attached to the inner tube with a longitudinal axis and bristles that are substantially perpendicular to the longitudinal axis of the brush, is not taught or suggested by either Zavada nor Edens et al., either individually or when combined.

In view of the distinct structural and functional features of the instantly recited device from that taught in the references cited in the Office Action, Applicants contend the instant claims are not anticipated nor made obvious by the cited references.

Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

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Respectfully submitted,

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